CENTER FOR DRUG EVALUATION AND RESEARCH

LIST OF GUIDANCE DOCUMENTS

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Internet (I): http://www.fda.gov/cder/guidance.htm

Subject Categories

Advertising Guidances

Dissemination of Reprints of Certain Published, Original Data (I)	**Document #:** N/A **Issued:** 10/8/96 **FOD #:** N/A
Funded Dissemination of Reference Texts (I)	**Document #:** N/A **Issued:** 10/8/96 **FOD #:** N/A

Biopharmaceutic Draft Guidances

Antifungal (Draft Guidance) (topical)	**Document #:** N/A **Issued:** 2/24/90 **FOD #:** N/A
Antifungal (Draft Guidance) (vaginal)	**Document #:** N/A **Issued:** 2/24/90 **FOD #:** N/A
Draft Guidance on Waiver Policy	**Document #:** N/A **Issued:** 3/29/93 **FOD #:** N/A
Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling (I)	**Document #:** N/A **Issued:** 6/16/97 **FOD #:** 0820

Biopharmaceutic Guidances

Acetohexamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/1/88 **FOD #:** N/A
Albuterol Inhalation Aerosols (Metered Dose Inhalers) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 1/27/94 **FOD #:** N/A
Albuterol Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 5/29/87 **FOD #:** N/A
Allopurinol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 7/15/85 **FOD #:** N/A
Alprazolam Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 11/27/92 **FOD #:** 0303

Amiloride Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 3/29/85 **FOD #:** N/A
Aminophylline (suppositories) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 7/5/83 **FOD #:** N/A
Amitriptyline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 7/5/83 **FOD #:** N/A
Amoxapine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/5/88 **FOD #:** N/A
Amoxicillin (capsules, tablets and suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 6/10/88 **FOD #:** N/A
Approaches to Statistical Data Analysis of Bioavailability/Bioequivalence Studies	**Document #:** N/A **Issued:** 11/1/85 **FOD #:** N/A
Atenolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 10/6/88 **FOD #:** N/A
Baclofen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 5/5/86 **FOD #:** N/A
Bioavailability Policies and Guidelines	**Document #:** N/A **Issued:** **FOD #:** N/A
Biopharmaceutic Considerations in Designing and Evaluating Novel Drug Delivery Systems	**Document #:** N/A **Issued:** 11/1/83 **FOD #:** N/A
Bumetanide Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** 0304
Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 8/13/93 **FOD #:** 0305
Captopril Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 5/13/93 **FOD #:** N/A

Carbamazepine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 1/20/88 **FOD #:** N/A
Carbidopa and Levodopa Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 6/19/92 **FOD #:** 0306
Cefaclor Capsules and Suspension In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** 0307
Cefadroxil (capsules, tablets and suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 10/7/86 **FOD #:** N/A
Cephalexin (tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 3/19/87 **FOD #:** N/A
Cholestyramine Powder In Vitro Bioequivalence (Interim Guidance) (I)	**Document #:** N/A **Issued:** 7/15/93 **FOD #:** 0308
Climetidine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 6/12/92 **FOD #:** 0309
Clindamycin Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 5/31/88 **FOD #:** N/A
Clozapine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 11/15/95 **FOD #:** 0334
Conjugated Estrogens (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/21/91 **FOD #:** N/A
Controlled Release Dosage Forms: Issues and Controversies	**Document #:** N/A **Issued:** 9/10/85 **FOD #:** N/A
Corticosteroids, Dermatologic (topical) In Vivo	**Document #:** N/A **Issued:** 6/2/95 **FOD #:** 0316
Cyclobenzaprine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 1/25/88 **FOD #:** N/A

Diclofenac Sodium (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 10/6/94 **FOD #:** N/A
Diflunisal Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 6/16/92 **FOD #:** 0311
Diltiazem Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 5/16/92 **FOD #:** 0312
Division Guidelines for the Evaluation of Controlled Release Drug Products	**Document #:** N/A **Issued:** **FOD #:** N/A
Estropipate Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 8/26/92 **FOD #:** 0313
Fenoprofen (capsules and tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 2/3/88 **FOD #:** N/A
Flurazepam Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 10/15/85 **FOD #:** N/A
Flurbiprofen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 6/8/95 **FOD #:** N/A
Gemfibrozil Capsules or Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 6/15/92 **FOD #:** 0317
Glipizide In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** 0318
Glyburide Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** N/A
Guanabenz Acetate Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** 0319
Guidance on Statistical Procedure for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design	**Document #:** N/A **Issued:** 7/1/92 **FOD #:** 0330

Guideline for Dissolution Testing	**Document #:** N/A **Issued:** 4/1/78 **FOD #:** N/A
Guideline for the Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application*	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2008
Haloperidol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 4/30/87 **FOD #:** N/A
Hydrochlorothiazide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/28/87 **FOD #:** N/A
Hydroxychloroquine Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 12/28/95 **FOD #:** 0333
Hydroxyzine Hydrochloride (tablets) (dissolution only)	**Document #:** N/A **Issued:** 3/4/86 **FOD #:** N/A
Hydroxyzine Pamoate (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/28/87 **FOD #:** N/A
In Vivo Bioequivalence Studies of Clozapine	**Document #:** N/A **Issued:** 4/22/96 **FOD #:** N/A
Indapamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** 0320
Indomethacin (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 1/27/88 **FOD #:** N/A
Informal Guidance on the Submission of Data for Bioequivalence Studies in Computer Format	**Document #:** N/A **Issued:** **FOD #:** N/A
Isopropamide Iodide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 5/12/82 **FOD #:** N/A
Isosorbide Dinitrate (chewable tablets, oral tablets, and sublingual tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/22/87 **FOD #:** N/A

Ketoprofen (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** 0321
Leucovorin Calcium (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/4/88 **FOD #:** N/A
Lorazepam (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/16/87 **FOD #:** N/A
Loxapine Succinate (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/10/87 **FOD #:** N/A
Maprotiline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/27/87 **FOD #:** N/A
Meclofenamate Sodium (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 11/12/86 **FOD #:** N/A
Medroxyprogesterone Acetate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/17/87 **FOD #:** N/A
Megestrol Acetate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/17/87 **FOD #:** N/A
Metaproterenol Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 3/18/88 **FOD #:** N/A
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	**Document #:** N/A **Issued:** 6/27/89 **FOD #:** N/A
Methylprednisolone (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 6/12/86 **FOD #:** N/A
Metoclopramide Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 12/27/84 **FOD #:** N/A
Metoprolol Tartrate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 6/12/92 **FOD #:** 0322

Nadolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 5/16/92 **FOD #:** 0323
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Norethindrone and Ethinyl Estradiol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 3/18/88 **FOD #:** N/A
Norethindrone and Mestranol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 5/13/88 **FOD #:** N/A
Nortriptyline Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 6/12/92 **FOD #:** 0325
Oral Extended (controlled) Release In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	**Document #:** N/A **Issued:** 9/9/93 **FOD #:** 0310
Orphenadrine Citrate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 7/22/83 **FOD #:** N/A
Pentoxifylline (extended-release tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 12/22/95 **FOD #:** 0331
Perphenazine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/27/87 **FOD #:** N/A
Perphenazine/Amitriptyline (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/27/87 **FOD #:** N/A
Pharmacokinetic Considerations in Drug Studies	**Document #:** N/A **Issued:** **FOD #:** N/A
Phenylbutazone Oxyphenbutazone (capsules and tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/28/87 **FOD #:** N/A

Phenytoin/Phenytion Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 3/4/94 **FOD #:** 0326
Pindolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** 0327
Piroxicam (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 6/15/92 **FOD #:** 0328
Potassium Chloride (slow-release tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 5/15/87 **FOD #:** N/A
Prazepam (capsules and tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 7/26/88 **FOD #:** N/A
Prednisone (tablets) (dissolution only)	**Document #:** N/A **Issued:** 7/10/85 **FOD #:** N/A
Propranolol Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/1/84 **FOD #:** N/A
Propylthiouracil (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/13/86 **FOD #:** N/A
Quinidine Gluconate (tablets, controlled release) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 6/15/87 **FOD #:** N/A
Ranitidine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 4/23/93 **FOD #:** 0329
Regulatory Aspects Pertinent to the Development of Transdermal Drug Delivery Systems	**Document #:** N/A **Issued:** **FOD #:** N/A
Rifampin (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/8/88 **FOD #:** N/A
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Selegiline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 12/22/95 **FOD #:** 0332
Silver Sulfadiazine (cream)	**Document #:** N/A **Issued:** 5/7/87 **FOD #:** N/A
Sulfasalazine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 10/8/87 **FOD #:** N/A
Sulfones (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 11/7/86 **FOD #:** N/A
Sulindac (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 7/18/88 **FOD #:** N/A
Terfenadine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/11/95 **FOD #:** 0300
Theophylline (conventional dosage form) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 9/1/84 **FOD #:** N/A
Timolol Maleate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/9/88 **FOD #:** N/A
Tolazamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 5/30/86 **FOD #:** N/A
Tolbutamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 12/1/83 **FOD #:** N/A
Tolmetin Sodium (tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 10/6/94 **FOD #:** 0315
Trazodone Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 4/30/88 **FOD #:** N/A
Triazolam (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 12/24/92 **FOD #:** N/A

Trimipramine Maleate (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 8/18/87 **FOD #:** N/A
Verapamil Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	**Document #:** N/A **Issued:** 7/18/85 **FOD #:** N/A

Chemistry Draft Guidances

Draft Guidance: Tracking of NDA and ANDA Reformulations for Solid, Oral, Immediate Release Drug Products	**Document #:** 89N-0066 **Issued:** **FOD #:** N/A
Draft Guideline for Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications*	**Document #:** N/A **Issued:** 11/1/91 **FOD #:** 2009
Manufacturing Equipment Addendum to the Guidance for Industry for Scale-up and Post-Approval Changes: Immediate-Release Products (SUPAC-IR) (I)	**Document #:** N/A **Issued:** 2/3/97 **FOD #:** 0809

Chemistry Guidances

FDA's Policy Statement for the Development of New Stereoisomeric Drugs (I)	**Document #:** N/A **Issued:** 5/1/92 **FOD #:** N/A
Guidance for Industry: For the Submission of an Environmental Assessment in Human Drug Applications and Supplements (I)	**Document #:** CMC 6 **Issued:** 11/13/95 **FOD #:** 0803
Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptide Substances (I)	**Document #:** CMC 4 **Issued:** 11/1/94 **FOD #:** 0802
Guidance for Industry: For the Submission of Documentation for Sterilization Process Validation Applications for Human and Veterinary Drug Products (I)	**Document #:** CMC 2 **Issued:** 11/1/94 **FOD #:** 0800
Guidance for Industry: Format and Content for the CMC Section of an Annual Report (I)	**Document #:** CMC 1 **Issued:** 9/1/94 **FOD #:** 0801
Guidance for Industry: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (SUPAC IR) (I)	**Document #:** CMC 5 **Issued:** 11/30/95 **FOD #:** 0805
Guideline for Drug Master Files (I)	**Document #:** N/A **Issued:** 9/1/89 **FOD #:** 4001

Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics* (I)	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2006
Guideline for Submitting Documentation for the Manufacturing of and Controls for Drug Products*	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2000
Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics*	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2013
Guideline for Submitting Samples and Analytical Data for Methods Validation* (I)	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2002
Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances* (I)	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2012
Guideline for the Format and Content of the Chemistry, Manufacturing and Controls Section of an Application*	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2003
Guideline for the Format and Content of the Microbiology Section of an Application*	**Document #:** 85D-0245 **Issued:** 2/1/87 **FOD #:** 2001
Guideline on Sterile Drug Products Produced by Aseptic Processing	**Document #:** N/A **Issued:** 5/1/87 **FOD #:** 2014
Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation (SUPAC SS) (I)	**Document #:** CMC 7 **Issued:** 6/13/97 **FOD #:** 0819
Reviewer Guidance: Validation of Chromatographic Methods (I)	**Document #:** CMC 3 **Issued:** 11/1/94 **FOD #:** N/A

Clinical Draft Guidances

Draft Guideline for Abuse Liability Assessment	**Document #:** N/A **Issued:** 7/1/90 **FOD #:** N/A
Draft Guideline for Clinical Evaluation of Anti-Anginal Drugs	**Document #:** N/A **Issued:** 1/1/89 **FOD #:** N/A

Draft Guideline for Clinical Evaluation of Anti-Arrhythmic Drugs	**Document #:** N/A **Issued:** 7/1/85 **FOD #:** N/A
Draft Guideline for Clinical Evaluation of Drugs for Ulcerative Colitis (3rd draft)	**Document #:** N/A **Issued:** **FOD #:** N/A
Draft Guideline for the Clinical Evaluation of Motility-Modifying Drugs	**Document #:** N/A **Issued:** **FOD #:** N/A
Draft Guideline for the Clinical Evaluation of Weight-Control Drugs	**Document #:** N/A **Issued:** 11/29/94 **FOD #:** N/A
Draft Guideline for the Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders	**Document #:** N/A **Issued:** 2/12/92 **FOD #:** N/A
Draft Guidelines for Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis	**Document #:** N/A **Issued:** 4/1/94 **FOD #:** N/A
Draft Points to Consider in the Preparation of IND Applications for New Drugs Intended for the Treatment of HIV-Infected Individuals	**Document #:** N/A **Issued:** 9/1/91 **FOD #:** N/A
Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (I)	**Document #:** N/A **Issued:** 1/10/97 **FOD #:** 0806
Guidance for Industry: Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products (I)	**Document #:** N/A **Issued:** 2/18/97 **FOD #:** 0810
Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products (I)	**Document #:** N/A **Issued:** 3/13/97 **FOD #:** 0813
Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (I)	**Document #:** N/A **Issued:** 3/13/97 **FOD #:** 0812
Points to Consider for System Inflammatory Response Syndrome (SIRS) 1st Draft	**Document #:** N/A **Issued:** **FOD #:** N/A
Proposed Guidelines for the Clinical Evaluation of Antihypertensive Drugs	**Document #:** N/A **Issued:** 5/1/88 **FOD #:** N/A

Proposed Guidelines for the Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure	**Document #:** N/A **Issued:** 12/1/87 **FOD #:** N/A

Clinical Guidances

Clinical Evaluation of Antacid Drugs	**Document #:** FDA 78-3065 **Issued:** 4/1/78 **FOD #:** 9000
Clinical Evaluation of Anti-Infective Drugs (Systemic)	**Document #:** FDA 77-3046 **Issued:** 11/1/92 **FOD #:** N/A
Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children)	**Document #:** N/A **Issued:** 5/26/93 **FOD #:** N/A
Clinical Evaluation of Antianxiety Drugs	**Document #:** FDA 77-3043 **Issued:** **FOD #:** N/A
Clinical Evaluation of Antidepressant Drugs	**Document #:** FDA 77-3042 **Issued:** 9/1/77 **FOD #:** N/A
Clinical Evaluation of Antidiarrheal Drugs	**Document #:** FDA 78-3049 **Issued:** 9/1/77 **FOD #:** N/A
Clinical Evaluation of Antiepileptic Drugs (adults and children)	**Document #:** FDA 81-3110 **Issued:** 1/1/81 **FOD #:** N/A
Clinical Evaluation of Bronchodilator Drugs	**Document #:** FDA 79-3073 **Issued:** **FOD #:** N/A
Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women	**Document #:** N/A **Issued:** 3/20/95 **FOD #:** N/A
Clinical Evaluation of Drugs to Prevent Dental Caries	**Document #:** FDA 79-3075 **Issued:** 11/1/78 **FOD #:** N/A
Clinical Evaluation of Drugs to Prevent, Control and/or Treat Periodontal Disease	**Document #:** FDA 79-3074 **Issued:** 11/1/78 **FOD #:** N/A

Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs	**Document #:** FDA 78-3050 **Issued:** 9/1/77 **FOD #:** N/A
Clinical Evaluation of General Anesthetics	**Document #:** FDA 82-3052 **Issued:** 5/1/82 **FOD #:** 9002
Clinical Evaluation of Hypnotic Drugs	**Document #:** FDA 78-3051 **Issued:** 9/1/77 **FOD #:** N/A
Clinical Evaluation of Laxative Drugs	**Document #:** FDA 78-3067 **Issued:** 4/1/78 **FOD #:** N/A
Clinical Evaluation of Lipid-Altering Agents in Adults and Children	**Document #:** FDA 80-3103 **Issued:** **FOD #:** N/A
Clinical Evaluation of Local Anesthetics	**Document #:** FDA 82-3053 **Issued:** 5/1/82 **FOD #:** N/A
Clinical Evaluation of Psychoactive Drugs in Infants and Children	**Document #:** FDA 79-3055 **Issued:** 7/1/79 **FOD #:** N/A
Clinical Evaluation of Radiopharmaceutical Drugs	**Document #:** FDA 81-3120 **Issued:** 10/1/81 **FOD #:** N/A
FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer	**Document #:** N/A **Issued:** 1/29/91 **FOD #:** N/A
FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer	**Document #:** N/A **Issued:** 6/20/89 **FOD #:** N/A
General Considerations for the Clinical Evaluation of Drugs	**Document #:** FDA 77-3040 **Issued:** 12/1/78 **FOD #:** 9001
General Considerations for the Clinical Evaluation of Drugs in Infants and Children	**Document #:** FDA 77-3041 **Issued:** **FOD #:** N/A
Guidance for Industry: Content and Format for Pediatric Use Supplements (I)	**Document #:** CLIN 1 **Issued:** 5/24/96 **FOD #:** 0808

Guidance for Industry: Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (I)	**Document #:** CLIN 2 **Issued:** 11/20/95 **FOD #:** 0804
Guidance for Industry: Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (I)	**Document #:** CLIN 3 **Issued:** 4/7/97 **FOD #:** 0816
Guidance for the Development of Vaginal Contraceptive Drugs (NDA)	**Document #:** 95D-0004 **Issued:** 4/19/95 **FOD #:** N/A
Guideline for Clinical Evaluation of Analgesic Drugs	**Document #:** FDA 93-3093 **Issued:** 12/1/92 **FOD #:** N/A
Guideline for Postmarketing Reporting of Adverse Drug Experiences	**Document #:** 85D-0249 **Issued:** 3/1/92 **FOD #:** N/A
Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications* (I)	**Document #:** N/A **Issued:** 7/1/88 **FOD #:** N/A
Guideline for the Format and Content of the Summary for New Drug and Antibiotic Applications*	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2004
Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs	**Document #:** N/A **Issued:** 7/22/93 **FOD #:** N/A
Guideline for the Study of Drugs Likely to be Used in the Elderly	**Document #:** N/A **Issued:** 11/1/89 **FOD #:** N/A
Guideline on Formatting, Assembling and Submitting New Drug and Antiobiotic Applications*	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2007
Guideline on the Preparation of Investigational New Drug Products (Human and Animal)	**Document #:** N/A **Issued:** 3/1/91 **FOD #:** 0600
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer	**Document #:** N/A **Issued:** 4/13/88 **FOD #:** N/A
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Colon and Rectal Cancer	**Document #:** N/A **Issued:** **FOD #:** N/A

Points to Consider in the Clinical Development and Labeling of Anti-Infective Drug Products	**Document #:** N/A **Issued:** 10/26/92 **FOD #:** N/A
Points to Consider in the Preclinical Development of Antiviral Drugs	**Document #:** N/A **Issued:** 11/1/90 **FOD #:** N/A
Points to Consider in the Preclinical Development of Immunomodulatory Drugs for the Treatment of HIV Infection and Associated Disorders	**Document #:** N/A **Issued:** 5/1/93 **FOD #:** 1001
Points to Consider: Clinical Development Programs for MDI and DPI Drug Products	**Document #:** N/A **Issued:** 9/19/94 **FOD #:** 1000

Compliance Draft Guidances

Computerized Systems Used in Clinical Trials (I)	**Document #:** N/A **Issued:** 6/18/97 **FOD #:** N/A
Draft Guideline on Supplements to New Applications, Abbreviated New Drug Applications or Abbreviated Antibiotic Applications for Nonsterile Drug Products	**Document #:** 93D-0403 **Issued:** 12/12/94 **FOD #:** N/A
Guidance for Industry: Manufacture, Processing or Holding of Active Pharmaceutical Ingredients (I)	**Document #:** N/A **Issued:** 9/20/96 **FOD #:** N/A

Compliance Guidances

A Review of FDA's Implementation of the Drug Export Amendments of 1986	**Document #:** N/A **Issued:** **FOD #:** N/A
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (I)	**Document #:** CP 2 **Issued:** 6/27/97 **FOD #:** 0824
Good Laboratory Practice Regulations Questions and Answers	**Document #:** N/A **Issued:** **FOD #:** N/A
Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products (I)	**Document #:** CP 1 **Issued:** 4/22/97 **FOD #:** 0815
Guideline for Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices	**Document #:** N/A **Issued:** 12/1/87 **FOD #:** N/A

Guideline on Compressed Medical Gases (I)	**Document #:** N/A **Issued:** 12/1/89 **FOD #:** N/A
Guideline on General Principles of Process Validation (I)	**Document #:** N/A **Issued:** 5/1/87 **FOD #:** N/A
Monitoring of Clinical Investigations	**Document #:** N/A **Issued:** 1/1/88 **FOD #:** N/A
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment	**Document #:** N/A **Issued:** 5/1/84 **FOD #:** N/A

Generic Drug Draft Guidances

Guidance for Industry: Content and Format of an Abbreviated New Drug Application (ANDA) - Positron Emission Tomography (PET) Drug Products - With specific information for ANDAs for Fludeoxyglucose F18 Injection (I)	**Document #:** N/A **Issued:** 4/18/97 **FOD #:** 0817

Generic Drug Guidances

Guidance for Industry: Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application (I)	**Document #:** OGD 1 **Issued:** 4/7/97 **FOD #:** 0814
Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past.	**Document #:** N/A **Issued:** 8/18/95 **FOD #:** N/A
Letter describing efforts by the CDER and the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new and abbreviated drug approval process in order to reduce duplication or redundancy in the	**Document #:** N/A **Issued:** 10/14/94 **FOD #:** N/A
Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy	**Document #:** N/A **Issued:** 4/8/94 **FOD #:** N/A
Letter on the provision of information and guidance about the performance of in vivo bioequivalence (or any pharmacokinetic) studies of clozapine (Clozaril, Sandoz Pharmaceuticals Corporation)	**Document #:** N/A **Issued:** 1/31/95 **FOD #:** N/A
Letter on the provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters	**Document #:** N/A **Issued:** 7/1/92 **FOD #:** N/A
Letter on the provision of new procedures and policies affecting the generic drug review process	**Document #:** N/A **Issued:** 3/15/89 **FOD #:** N/A

Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions	**Document #:** N/A **Issued:** 11/8/91 **FOD #:** N/A
Letter on the response to 12/20/84 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act	**Document #:** N/A **Issued:** 3/26/85 **FOD #:** N/A
Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law	**Document #:** N/A **Issued:** 1/15/93 **FOD #:** N/A
Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria, and bioequivalence requirements	**Document #:** N/A **Issued:** 8/4/93 **FOD #:** N/A
Positron Emission Tomography Questions and Answers 1 (I)	**Document #:** N/A **Issued:** 10/24/96 **FOD #:** N/A
Positron Emission Tomography Questions and Answers 2 (I)	**Document #:** N/A **Issued:** 4/18/97 **FOD #:** N/A

ICH Draft Guidances

Biotechnological/Biological Pharmaceutical Products, Viral Safety Evaluation (I)	**Document #:** ICH Q5A **Issued:** 5/10/96 **FOD #:** 7010
Carcinogenicity Studies of Pharmaceuticals: Addendum to Dose Selection (I)	**Document #:** ICH S1C (R) **Issued:** 4/2/97 **FOD #:** 0821
Data Elements for Transmission of Individual Case Reports (I)	**Document #:** ICH E2B **Issued:** 10/1/96 **FOD #:** N/A
General Considerations for Clinical Trials (I)	**Document #:** ICH E8 **Issued:** 5/30/97 **FOD #:** 7025
Genotoxicity: Standard Battery Testing (I)	**Document #:** ICH S2B **Issued:** 4/3/97 **FOD #:** 7027
Impurities: Residual Solvents (I)	**Document #:** ICH Q3C **Issued:** 5/2/97 **FOD #:** 7023

Preclinical Testing of Biotechnology-Derived Pharmaceuticals (I)	**Document #:** ICH S6 **Issued:** 4/4/97 **FOD #:** 7028
Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products (I)	**Document #:** ICH Q5D **Issued:** 5/2/97 **FOD #:** 7022
Statistical Principles for Clinical Trials (I)	**Document #:** ICH E9 **Issued:** 5/9/97 **FOD #:** 7018
Testing for Carcinogenicity in Pharmaceuticals (I)	**Document #:** ICH S1B **Issued:** 8/21/96 **FOD #:** 7016
Timing of Nonclinical Studies for the Conduct of Human Clinical Trials for Pharmaceuticals (I)	**Document #:** ICH M3 **Issued:** 5/2/97 **FOD #:** 7021

ICH Guidances

Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies (I)	**Document #:** ICH S3B **Issued:** 3/1/95 **FOD #:** 7011
Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (I)	**Document #:** ICH E2A **Issued:** 3/1/95 **FOD #:** 0822
Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (I)	**Document #:** ICH E2C **Issued:** 5/19/97 **FOD #:** 7024
Detection of Toxicity to Reproduction for Medicinal Products (I)	**Document #:** ICH S5A **Issued:** 9/22/94 **FOD #:** 7000
Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility (I)	**Document #:** ICH S5B **Issued:** 4/5/96 **FOD #:** 7000
Dose Selection for Carcinogenicity Studies of Pharmaceuticals (I)	**Document #:** ICH S1C **Issued:** 3/1/95 **FOD #:** N/A
Dose-Response Information to Support Drug Registration (I)	**Document #:** ICH E4 **Issued:** 11/9/94 **FOD #:** N/A

Good Clinical Practice: Consolidated Guideline (I)	**Document #:** ICH E6 **Issued:** 5/9/97 **FOD #:** 7026
Impurities in New Drug Products (I)	**Document #:** ICH Q3B **Issued:** 5/19/97 **FOD #:** 7019
Impurities in New Drug Substances (I)	**Document #:** ICH Q3A **Issued:** 1/4/96 **FOD #:** 7007
Photostability Testing of New Drug Substances and Products (I)	**Document #:** ICH Q1B **Issued:** 5/16/97 **FOD #:** 7004
Quality of Biotechnological Products: Stability Testing of Biotechnology/Biological Products (I)	**Document #:** ICH Q5C **Issued:** 7/10/96 **FOD #:** 7014
Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products (I)	**Document #:** ICH Q5B **Issued:** 2/23/96 **FOD #:** 7006
Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals (I)	**Document #:** ICH S2A **Issued:** 4/24/96 **FOD #:** N/A
Stability Testing for New Dosage Forms (I)	**Document #:** ICH Q1C **Issued:** 5/9/97 **FOD #:** 7017
Stability Testing of New Drug Substances and Products (I)	**Document #:** ICH Q1A **Issued:** 9/22/94 **FOD #:** N/A
Structure and Content of Clinical Study Reports (I)	**Document #:** ICH E3 **Issued:** 7/17/96 **FOD #:** 7017
Studies in Support of Special Populations: Geriatrics (I)	**Document #:** ICH E7 **Issued:** 8/2/94 **FOD #:** N/A
Text on Validation of Analytical Procedures (I)	**Document #:** ICH Q2A **Issued:** 3/1/95 **FOD #:** N/A
The Extent of Population Exposure to Assess Clinical Safety: for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions (I)	**Document #:** ICH E1A **Issued:** 3/1/95 **FOD #:** 7012

The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals (I)	**Document #:** ICH S1A **Issued:** 3/1/96 **FOD #:** 7008
Toxicokinetics: The Assessment of systemic Exposure in Toxicity Studies (I)	**Document #:** ICH S3A **Issued:** 3/1/95 **FOD #:** 7013
Validation of Analytical Procedures: Methodology (I)	**Document #:** ICH Q2B **Issued:** 5/19/97 **FOD #:** 7020

Industry Letters

Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program	**Document #:** N/A **Issued:** 6/1/90 **FOD #:** N/A
Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required	**Document #:** N/A **Issued:** 4/10/87 **FOD #:** N/A
Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I	**Document #:** N/A **Issued:** 10/31/86 **FOD #:** N/A
Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance	**Document #:** N/A **Issued:** 10/11/84 **FOD #:** N/A
Implementation Plan USP injection nomenclature	**Document #:** N/A **Issued:** 10/2/95 **FOD #:** N/A
Seventh of a series of letters about the Act providing guidance on the "130-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C	**Document #:** N/A **Issued:** 7/29/88 **FOD #:** N/A
Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act	**Document #:** N/A **Issued:** 4/28/88 **FOD #:** N/A
Supplement to 10/11/84 letter about policies, procedures and implementation of the Act (Q & A format)	**Document #:** N/A **Issued:** 11/16/84 **FOD #:** N/A
Third of a series of letters regarding the implementation of the Act	**Document #:** N/A **Issued:** 5/1/85 **FOD #:** N/A

Information Technology Draft Guidances

Guidance for Industry: Electronic Submission of Case Report Forms and Case Report Tabulations (I)	**Document #:** N/A **Issued:** 11/4/96 **FOD #:** N/A
Guidance for Industry: Submitting Application Archival Copies in Electronic Format (I)	**Document #:** N/A **Issued:** 11/4/96 **FOD #:** N/A

Information Technology Guidances

CANDA (Computer Assisted New Drug Application) Guidance Manual	**Document #:** 92D-0296 **Issued:** 10/1/94 **FOD #:** N/A

Labeling Guidances

Acetaminophen and Codeine Phosphate Oral Solution/Suspension	**Document #:** N/A **Issued:** 12/1/93 **FOD #:** 0906
Acetaminophen and Codeine Phosphate Tablets/Capsules	**Document #:** N/A **Issued:** 12/1/93 **FOD #:** 0907
Acetaminophen, Aspirin and Codeine Phosphate Tablets/Capsules (I)	**Document #:** N/A **Issued:** 12/1/93 **FOD #:** 0905
Alprazolam Tablets	**Document #:** N/A **Issued:** 5/1/93 **FOD #:** 0903
Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP (I)	**Document #:** N/A **Issued:** 10/1/92 **FOD #:** 0904
Antihistamine Guidance	**Document #:** N/A **Issued:** 4/1/83 **FOD #:** N/A
Atenolol Tablets (I)	**Document #:** N/A **Issued:** 6/1/95 **FOD #:** 0908
Barbiturate, Single Entity-Class Labeling	**Document #:** N/A **Issued:** 3/1/81 **FOD #:** N/A

Butalbital, Acetaminophen and Caffeine Capsules/Tablets (I)	**Document #:** N/A **Issued:** 4/1/93 **FOD #:** 0909
Butorphanol Tartrate Injection USP (I)	**Document #:** N/A **Issued:** 10/1/92 **FOD #:** 0910
Captopril and Hydrochlorothiazide Tablets (I)	**Document #:** N/A **Issued:** 4/1/95 **FOD #:** 0911
Captopril Tablets	**Document #:** N/A **Issued:** 2/1/95 **FOD #:** 0912
Carbidopa and Levodopa Tablets (I)	**Document #:** N/A **Issued:** 2/1/92 **FOD #:** 0913
Chlordiazepoxide Hydrochloride Capsules	**Document #:** N/A **Issued:** 1/1/88 **FOD #:** N/A
Cimetidine Hydrochloride Injection (I)	**Document #:** N/A **Issued:** 9/1/95 **FOD #:** 0914
Cimetidine Tablets (I)	**Document #:** N/A **Issued:** 9/1/95 **FOD #:** N/A
Clindamycin Phosphate Injection USP (I)	**Document #:** N/A **Issued:** 5/1/92 **FOD #:** 0915
Clorazepate Dipotassium Capsules/Tablets	**Document #:** N/A **Issued:** 3/1/93 **FOD #:** N/A
Cyproheptadine Hydrochloride Tablets/Syrup	**Document #:** N/A **Issued:** 12/1/86 **FOD #:** N/A
Diclofenac Sodium Delayed-Release Tablets (I)	**Document #:** N/A **Issued:** 2/1/95 **FOD #:** 0916
Diltiazem Hydrochloride Extended-Release Capsules (twice a day dosage) (I)	**Document #:** N/A **Issued:** 9/1/95 **FOD #:** N/A

Diphenhydramine Hydrochloride Capsules/Elixir	**Document #:** N/A **Issued:** 6/1/86 **FOD #:** N/A
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution (I)	**Document #:** N/A **Issued:** 4/1/95 **FOD #:** 0922
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets (I)	**Document #:** N/A **Issued:** 4/1/95 **FOD #:** 0923
Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%	**Document #:** N/A **Issued:** 5/1/92 **FOD #:** N/A
Ergoloid Mesylates Tablets	**Document #:** N/A **Issued:** 1/1/88 **FOD #:** N/A
Ergotamine Tartrate and Caffeine Tablets and Suppositories	**Document #:** N/A **Issued:** **FOD #:** N/A
Estrogen Class Labeling Guidance	**Document #:** N/A **Issued:** 8/1/92 **FOD #:** N/A
Fludeoxyglucose F18 Injection (I)	**Document #:** N/A **Issued:** 1/1/97 **FOD #:** N/A
Flurbiprofen Tablets USP (I)	**Document #:** N/A **Issued:** 1/1/94 **FOD #:** 0917
Gentamicin Sulfate Ophthalmic Ointment and Solution (I)	**Document #:** N/A **Issued:** 4/1/92 **FOD #:** 0918
Glyburide Tablets	**Document #:** N/A **Issued:** 4/1/93 **FOD #:** N/A
Haloperidol Tablets/Oral Solution (concentrate)	**Document #:** N/A **Issued:** 2/1/90 **FOD #:** N/A
Heparin Sodium Injection USP (I)	**Document #:** N/A **Issued:** 3/1/91 **FOD #:** 0919

Hydrocodone Bitartrate and Acetaminophen Tablets (I)	**Document #:** N/A **Issued:** 4/1/94 **FOD #:** 0920
Hydroxyzine Hydrochloride Injection	**Document #:** N/A **Issued:** 12/1/89 **FOD #:** N/A
Hydroxyzine Hydrochloride Tablets/Syrup	**Document #:** N/A **Issued:** 5/1/86 **FOD #:** N/A
Hypoglycemic Oral Agents - Federal Register	**Document #:** N/A **Issued:** 4/1/84 **FOD #:** N/A
Indomethacin Capsules USP (I)	**Document #:** N/A **Issued:** 9/1/95 **FOD #:** N/A
Informal Labeling Guidance Texts for Estrogen Drug Products - Patient Labeling	**Document #:** N/A **Issued:** 12/1/92 **FOD #:** N/A
Informal Labeling Guidance Texts for Estrogen Drug Products - Professional Labeling	**Document #:** N/A **Issued:** 12/1/92 **FOD #:** N/A
Isoetharine Inhalation Solution	**Document #:** N/A **Issued:** 3/1/89 **FOD #:** N/A
Labeling Guidance for Combination Oral Contraceptives - Physician and Patient Labeling	**Document #:** N/A **Issued:** 1/1/94 **FOD #:** N/A
Leucovorin Calcium for Injection (I)	**Document #:** N/A **Issued:** **FOD #:** 0921
Local Anesthetics - Class Labeling	**Document #:** N/A **Issued:** 9/1/82 **FOD #:** N/A
Meclofenamate Sodium Capsules	**Document #:** N/A **Issued:** 7/1/92 **FOD #:** N/A
Metaproterenol Sulfate Inhalation Solution, 5% (I)	**Document #:** N/A **Issued:** 5/1/92 **FOD #:** 0924

Metaproterenol Sulfate Syrup (I)	**Document #:** N/A **Issued:** 5/1/92 **FOD #:** 0925
Metaproterenol Sulfate Tablets (I)	**Document #:** N/A **Issued:** 5/1/92 **FOD #:** 0926
Metoclopramide Tablets USP/Oral Solution (I)	**Document #:** N/A **Issued:** 2/1/95 **FOD #:** N/A
Naphazoline Hydrochloride Ophthalmic Solution	**Document #:** N/A **Issued:** 3/1/89 **FOD #:** N/A
Naproxen Sodium Tablets (I)	**Document #:** N/A **Issued:** 2/1/95 **FOD #:** 0927
Naproxen Tablets (I)	**Document #:** N/A **Issued:** 2/1/95 **FOD #:** 0928
Niacin Tablets	**Document #:** N/A **Issued:** 7/1/92 **FOD #:** N/A
Phendimetrazine Tartrate Capsules/Tablets, and Extended-Release Capsules	**Document #:** N/A **Issued:** 2/1/91 **FOD #:** N/A
Phentermine Hydrochloride Capsules/Tablets	**Document #:** N/A **Issued:** 8/1/88 **FOD #:** N/A
Promethazine Hydrochloride Tablets	**Document #:** N/A **Issued:** 3/1/90 **FOD #:** N/A
Propantheline Bromide Tablets	**Document #:** N/A **Issued:** 8/1/88 **FOD #:** N/A
Pyridoxine Hydrochloride Injection	**Document #:** N/A **Issued:** 6/1/84 **FOD #:** N/A
Quinidine Sulfate Tablets/Capsules	**Document #:** N/A **Issued:** 10/1/95 **FOD #:** N/A

Ranitidine Tablets (I)	**Document #:** N/A **Issued:** 11/1/93 **FOD #:** 0929
Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension and Solution (I)	**Document #:** N/A **Issued:** 1/1/95 **FOD #:** 0932
Sulfacetamide Sodium Ophthalmic Solution/Ointment (I)	**Document #:** N/A **Issued:** 8/1/92 **FOD #:** 0931
Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets	**Document #:** N/A **Issued:** 2/1/92 **FOD #:** N/A
Sulfamethoxazole and Trimethoprim Tablets and Oral Suspension (I)	**Document #:** N/A **Issued:** 8/1/93 **FOD #:** 0930
Theophylline Immediate-Release Dosage Forms	**Document #:** N/A **Issued:** 2/1/95 **FOD #:** N/A
Theophylline Intravenous Dosage Forms	**Document #:** N/A **Issued:** 2/9/96 **FOD #:** 0933
Thiamine Hydrochloride Injection	**Document #:** N/A **Issued:** 2/1/88 **FOD #:** N/A
Tobramycin Sulfate Injection (I)	**Document #:** N/A **Issued:** 5/1/93 **FOD #:** 0934
Topical Corticosteroids Class Labeling	**Document #:** N/A **Issued:** **FOD #:** N/A
Verapamil Hydrochloride Tablets (I)	**Document #:** N/A **Issued:** 10/1/91 **FOD #:** 0935
Vitamin A Capsules	**Document #:** N/A **Issued:** 2/1/92 **FOD #:** N/A

OTC Draft Guidances

Draft Points to Consider for OTC Actual Use Studies	**Document #:** N/A **Issued:** 7/22/94 **FOD #:** N/A

OTC Guidances

Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16)	**Document #:** N/A **Issued:** **FOD #:** N/A
General Guidelines for OTC Combination Products	**Document #:** 78D-0322 **Issued:** **FOD #:** N/A
Guidelines for Upgrading Category III Antiperspirants to Category I (43 FR 46728-46731)	**Document #:** N/A **Issued:** **FOD #:** N/A

Pharmacology/Toxicology Guidances

Guideline for the Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application*	**Document #:** N/A **Issued:** 2/1/87 **FOD #:** 2005
Points to Consider in the Nonclinical Pharmacology/Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or for the Development of Drugs Intended to Act as Vaginal Contraceptives (I)	**Document #:** N/A **Issued:** **FOD #:** N/A
Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies	**Document #:** N/A **Issued:** 2/1/89 **FOD #:** N/A
Single Dose Acute Toxicity Testing Toxicity Testing for Pharmaceuticals (I)	**Document #:** PT 1 **Issued:** 8/26/96 **FOD #:** N/A

*A set of 13 guidance documents, formerly known as the "NDA Guidelines" or "Rainbow Pack," may be obtained from the Drug Information Branch.